DT17 2'd PCT/PTO JUN 2 5 2002

|   | M PTO<br>/ 11-20  |   | OF COMMERCE PATENT AND TRADEMARK OFFICE         | ATTORNEY'S DOCKET NUMBER 117-385                   |  |  |  |  |  |
|---|---|---|---|--|--|--|--|--|--|
| (1/12   | 7 11-20   |   | R TO THE UNITED STATES                          | U.S. APPLICATION NO. (If known, see 37 C.F.R. 1.5) |  |  |  |  |  |
|   |   |   | CTED OFFICE (DO/EO/US)                          | 10 /   |  |  |  |  |  |
|   |   | -   | ING UNDER 35 U.S.C. 371                         | 10/088,341   |  |  |  |  |  |
| INTERNATIONAL APPLICATION NO. IN PCT/GB00/03575   |   |   | INTERNATIONAL FILING DATE 18/09/2000            | PRIORITY DATE CLAIMED 17/09/1999                   |  |  |  |  |  |
| TIT   | TITLE OF INVENTION  |   |   |  |  |  |  |  |  |
|   | ORAL RECOMBINANT LACTOBACILLI VACCINES                            |   |   |  |  |  |  |  |  |
| API   | PLICA   | NT(S) FOR DO/EO/US  | SHAW, D. et al.                                 |  |  |  |  |  |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: |   |   |   |  |  |  |  |  |  |
| 1. This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.  |   |   |   |  |  |  |  |  |  |
| 2.  | $\boxtimes$   | This is a SECOND or SUBS  | EQUENT submission of items concerning a f       | iling under 35 U.S.C. 371.                         |  |  |  |  |  |
| 3.  |   | This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. |   |  |  |  |  |  |  |
| 4.  |   | The U.S. has been elected   | by the expiration of 19 months from the priorit | y date (Article 31).                               |  |  |  |  |  |
| 5.  | A co  |   | ation as filed (35 U.S.C. 371(c)(2)).           |  |  |  |  |  |  |
|   | a.  |   | uired only if not communicated by the Interna   | itional Bureau).                                   |  |  |  |  |  |
|   | b.  |   | ed by the International Bureau.                 | ,  |  |  |  |  |  |
|   | c.  | is not required, as the application was filed in the United States Receiving Office (RO/US).  |   |  |  |  |  |  |  |
| 6.  |   | An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).  |   |  |  |  |  |  |  |
|   | a.  | is attached hereto.   |   |  |  |  |  |  |  |
|   | b.  | has been previously s   | ubmitted under 35 U.S.C. 154(d)(4).             |  |  |  |  |  |  |
| 7.  |   | Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))  |   |  |  |  |  |  |  |
|   | a.  |   | equired only if not communicated by the Interr  |  |  |  |  |  |  |
|   | b.  |   | ited by the International Bureau.               | ,  |  |  |  |  |  |
|   | c.  | _   | nowever, the time limit for making such amend   | dments has <b>NOT</b> expired.                     |  |  |  |  |  |
|   | d.  | have not been made and will not be made.  |   |  |  |  |  |  |  |
| 8.  |   | An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).   |   |  |  |  |  |  |  |
| 9.  |   | An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).  |   |  |  |  |  |  |  |
| 10.   |   | A English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).                     |   |  |  |  |  |  |  |
|   | Items 11 To 20 below concern document(s) or information included: |   |   |  |  |  |  |  |  |
| 11.   |   | An Information Disclosure S   | tatement under 37 C.F.R. 1.97 and 1.98.         |  |  |  |  |  |  |
| 12.   | $\boxtimes$   | An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.  |   |  |  |  |  |  |  |
| 13.   |   | A FIRST preliminary amendment.  |   |  |  |  |  |  |  |
| 14.   |   | A SECOND or SUBSEQUENT preliminary amendment.   |   |  |  |  |  |  |  |
| 15.   |   | A substitute specification.   |   |  |  |  |  |  |  |
| 16.   |   | A change of power of attorney and/or address letter.  |   |  |  |  |  |  |  |
| 17.   |   | •   |   |  |  |  |  |  |  |
| 18.   |   | A second copy of the published international application under 35 U.S.C. 154(d)(4).   |   |  |  |  |  |  |  |
| 19.   |   | A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).   |   |  |  |  |  |  |  |
| 20  |   | Other items or information, CODY OF NOTIFICATION OF MISSING REQUIREMENTS LINDER 25 LLS C. S. 271  |   |  |  |  |  |  |  |

| 21. QIT the following loses are submitted: BASIC NATIONAL FEE FG CF.R. 1.432(1)(11-5): Neither international preliminary examination fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International preliminary examination fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International preliminary examination fee (37 C.F.R. 1.445(a)(2)) paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but international preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO and all claims did not satisfy provisions of PCT Article 33(1)-(4) \$70.00 \$10                              | U.S. APPLICATION NO. (If kno   |                  | R. 1.5)          | INTERNATIONAL APPLICA              |                | ,           | ATTO     | ORNEY'S DOCKET<br>117-385 | NUM | BER  |       |
|---|--|------------------|------------------|------------------------------------|----------------|-------------|----------|---------------------------|-----|------|-------|
| BASIC NATIONAL FEE (37 C.F.R. 1.432(N)(1)-5):   Nelther international periliminary examination fee (37 C.F.R. 1.482)   nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO and International search Report not prepared by the EPO or JPO  |  |                  |                  | PC1/GB00/035/                      | •              |             |          |                           |     |      |       |
| Neither international preliminary examination fee (37 C.F.R. 1482) nor international search Report not prepared by the EPO or JPO   |  |                  |                  | \ (=)                              |                |             | <u> </u> | ALCULATIONS               | PIC | 0350 | NLY - |
| International preliminary examination fee (37 C.F.R. 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$\  | Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO   |                  |                  |                                    |                |             |          |                           |     |      |       |
| but International search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO  | International preli  | minary exam      | ination fee (3   | 37 C.F.R. 1.482) not paid          | to             |             |          |                           |     |      |       |
| International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims did not satisfy provisions of PCT Article 33(1)-(4)  | International preli  | minary exam      | ination fee (3   | 37 C.F.R. 1.482) not paid to USPTO | to USPTO       | 3740 00     |          |                           |     |      |       |
| International preliminary examination fee (37 C.F.R. 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4)  | International preli  | minary exam      | ination fee (3   | 37 C.F.R. 1.482) paid to U         | SPTO           |             |          |                           |     |      |       |
| Surcharge of \$130.00 for furnishing the oath or declaration later than   | International preli  | minary exam      | ination fee (3   | 7 C.F.R. 1.482) paid to U          | SPTO           |             |          |                           |     |      |       |
| CLAIMS   NUMBER FILED   NUMBER EXTRA   RATE   | <u> </u>   | <b>F</b>         |                  |                                    |                |             | \$       | 0.00                      |     |      |       |
| CLAIMS   NUMBER FILED   NUMBER EXTRA   RATE   |  |                  |                  |                                    | □ 30           |             | \$       | 0.00                      |     |      |       |
| Independent Claims 3 3 3 0 X \$84.00 0.00    MULTIPLE DEPENDENT CLAIMS(S) (if applicable) \$280.00 \$ 0.00    Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  Processing fee of \$130.00, for furnishing the English Translation later than 20 30 0.00    Processing fee of \$130.00, for furnishing the English Translation later than 20 30 0.00    Fee for recording the enclosed assignment (37 C.F.R. 1.492(f)). ToTAL NATIONAL FEE \$ 0.00    Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property \$ 40.00    Fee for Petition to Revive Unintentionally Abandoned Application (\$1280.00 - Small Entity = \$640.00) \$ 0.00    TOTAL FEES ENCLOSED = \$ 40.00    Amount to be: refunded \$ Charged \$ \$    a.   |  |                  |                  |                                    | RA             | TE          |          |                           |     |      |       |
| MULTIPLE DEPENDENT CLAIMS(S) (if applicable)  TOTAL OF ABOVE CALCULATIONS = \$ 0.00  Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  SUBTOTAL = \$ 0.00  Processing fee of \$130.00, for furnishing the English Translation later than   |  |                  |                  | 0                                  |                |             | \$       | 0.00                      |     |      |       |
| Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 172.   0.00  | Independent Claims   | 3                | -3 =             | 0                                  | X              | \$84.00     |          | 0.00                      |     |      |       |
| Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  SUBTOTAL = \$ 0.00  Processing fee of \$130.00, for furnishing the English Translation later than  | MULTIPLE DEPENDEN  | T CLAIMS(S)      | ) (if applicabl  |                                    |                |             | \$       | 0.00                      |     |      |       |
| a. A check in the amount of \$40.00 to cover the above fees is enclosed.  By Please charge my Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.  C. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment of the entire content of the foreign applications), referred to in this application.  NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.  SEND ALL CORRESPONDENCE TO:  NIXON & VANDERHYE P.C.  100.00  Processing fee of \$130.00, for furnishing the English Translation later than 20 30 30 0.00  TOTAL NATIONAL FEE  |  |                  |                  |                                    |                | LATIONS =   | \$       | 0.00                      |     |      |       |
| Processing fee of \$130.00, for furnishing the English Translation later than   |  | •                | tus. See 37      | CFR 1.27. The fees indic           | ated above     |             |          | 0.00                      |     |      |       |
| months from the earliest claimed priority date (37 C.F.R. 1.492(f)). + 0.00  TOTAL NATIONAL FEE = \$ 0.00  Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property + \$ 40.00  Fee for Petition to Revive Unintentionally Abandoned Application (\$1280.00 – Small Entity = \$640.00) \$ 0.00  TOTAL FEES ENCLOSED = \$ 40.00  Amount to be: refunded \$ Charged \$ Ch                           | are reduced by 172.  |                  |                  |                                    | SU             | BTOTAL =    | \$       |                           |     |      |       |
| Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property  |  |                  |                  |                                    |                |             |          | 0.00                      |     |      |       |
| Fee for recording the enclosed assignment (37 C.F.R. 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property  | months from the earliest   | cialmed prior    | nty date (37     |                                    |                | NAL FEE =   | \$       |                           |     |      |       |
| Fee for Petition to Revive Unintentionally Abandoned Application (\$1280.00 - Small Entity = \$640.00) \$ 0.00  TOTAL FEES ENCLOSED = \$ 40.00  Amount to be: refunded \$ charged \$ c | Fee for recording the end  | closed assign    | nment (37 C.     | F.R. 1.21(h)). The assign          | ment must be   | +           |          |                           |     |      |       |
| TOTAL FEES ENCLOSED = \$ 40.00   Amount to be: refunded   \$   Charged   \$    a.   | Fee for Petition to Revive   | e Unintention    | ally Ahandor     | ned Application (\$1280.00         | - Small Entity | = \$640.00) |          |                           |     |      |       |
| a.  | 1 co for 1 cadori to 1 conve   | 2 01111101111011 | idily / Ibanidor |                                    |                |             |          |                           |     |      |       |
| a. A check in the amount of \$40.00 to cover the above fees is enclosed. b. Please charge my Deposit Account No. 14-1140 in the amount of \$ to cover the above fees. A duplicate copy of this form is enclosed. c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed. d. The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.  NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.  SEND ALL CORRESPONDENCE TO:  NIXON & VANDERHYE P.C. 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000 GRT:ap  Gary R. Tanigawa NAME  43,180  June 25, 2002  |  |                  |                  |                                    |                |             | À        |                           |     |      |       |
| a. A check in the amount of \$40.00 to cover the above fees is enclosed. b. Please charge my Deposit Account No. 14-1140 in the amount of \$ to cover the above fees. A duplicate copy of this form is enclosed. c. A the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed. d. The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.  NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.  SEND ALL CORRESPONDENCE TO:  NIXON & VANDERHYE P.C. 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000 GRT:ap  Gary R. Tanigawa NAME  43,180 June 25, 2002   |  |                  |                  |                                    |                |             |          |                           | \$  |      |       |
| <ul> <li>b. ☐ Please charge my Deposit Account No. 14-1140 in the amount of \$ to cover the above fees.         A duplicate copy of this form is enclosed.</li> <li>c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.</li> <li>d. ☑ The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.</li> <li>NOTE: Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</li> <li>SEND ALL CORRESPONDENCE TO:</li> <li>NIXON &amp; VANDERHYE P.C.</li> <li>1100 North Glebe Road, 8<sup>th</sup> Floor</li> <li>Arlington, Virginia 22201-4714</li> <li>Telephone: (703) 816-4000</li> <li>Gary R. Tanigawa</li> <li>NAME</li> <li>43,180</li> <li>June 25, 2002</li> </ul>   |  |                  |                  |                                    |                |             |          | Charged                   | \$  |      |       |
| SEND ALL CORRESPONDENCE TO:  NIXON & VANDERHYE P.C. 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000 GRT:ap  Gary R. Tanigawa NAME  43,180 June 25, 2002   | <ul> <li>b. Please charge my Deposit Account No. 14-1140 in the amount of \$ to cover the above fees. A duplicate copy of this form is enclosed.</li> <li>c. Mean Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.</li> <li>d. Mean Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1140. A duplicate copy of this form is enclosed.</li> <li>d. The entire content of the foreign application(s), referred to in this application is/are hereby incorporated by reference in this application.</li> </ul> |                  |                  |                                    |                |             |          |                           |     |      |       |
| NIXON & VANDERHYE P.C.  1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000 GRT:ap  Gary R. Tanigawa NAME  43,180 June 25, 2002   |  |                  |                  |                                    |                |             |          |                           |     |      |       |
| 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000 GRT:ap  Gary R. Tanigawa NAME  43,180 June 25, 2002   | SEND ALL CORRESPONDENCE TO:  |                  |                  |                                    |                |             |          |                           |     |      |       |
| 43,180 June 25, 2002  | 1100 North Glebe Road, 8 <sup>th</sup> Floor Arlington, Virginia 22201-4714 Telephone: (703) 816-4000  Gary R. Tanigawa  Gary R. Tanigawa  |                  |                  |                                    |                |             |          |                           |     |      |       |
|   | GRT:ap   |                  |                  |                                    | NAME           |             |          |                           |     |      |       |
| REGISTRATION NUMBER Date  |  |                  |                  |                                    |                | ĒR          |          | 002                       |     | -    |       |

# PTOTCT Rec'd 25 JUN 2002



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

**SHAW** 

Atty. Ref.: 117-385

Appln. No. 10/088,341

Group Art Unit: Not Known

Filed: March 18, 2002

Examiner: Not Known

FOR: ORAL RECOMBINANT LACTOBACILLI VACCINES

## RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. § 371

June 25, 2002

Hon. Commissioner for Patents Washington, D.C. 20231

Sir:

In response to the Notification of Missing Requirements mailed May 30, 2002, (copy attached), Applicants submit an executed inventors' Declaration in compliance with 35 U.S.C.§ 371.

Applicants earnestly solicit issuance of the Official filing receipt and an early examination on the merits. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By:

Garly R. Tanigawa Reg. No. 43,180

1100 North Glebe Road, 8th Floor Arlington, VA 22201-4714

Telephone: (703) 816-4000 Facsimile: (703) 816-4100





#### UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT Umted States Patent and Trademark Office Washington, D.C. 20231

| U.S. APPLICATION NUMBER N              | O. FIRST NAMED APPLICANT | ATTY. DOC  | KET NO.      |  |  |
|--|--------------------------|--|--------------|--|--|
| 10/088,341                             | Gary R Tanigawa          | 117-385  |              |  |  |
|  |                          | INTERNATIONAL APPLICATION NO. PCT/GB00/03575                     |              |  |  |
|  | DOCKETED                 |  |              |  |  |
| Nixon & Vanderhye                      | CIT/MANTIER# 119-385     | I.A. FILING DATE PI  | RIORITY DATE |  |  |
| 1100 North Glebe Road                  | CLI/IVIALILITY           | 09/18/2000   | 09/17/1999   |  |  |
| 8 th Floor<br>Arlington, VA 22201-4714 | MAIL DATE                | CONFIRMATION NO. 9257 371 FORMALITIES LETTER -OC000000008173069* |              |  |  |

Date Mailed: 05/30/2002

# NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- U.S. Basic National Fees
- Priority Document
- Copy of IPE Report
- Copy of references cited in ISR
- Copy of the International Application
- Copy of the International Search Report
- Preliminary Amendments
- Request for Immediate Examination

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

• Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTH FROM THE DATE OF THIS NOTICE OR BY 22 or 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

### VONDA M WALLACE

Telephone: (703) 305-3736

### PART 1 - ATTORNEY/APPLICANT COPY

| Γ | U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|---|-----------------------------|-------------------------------|------------------|
|   | 10/088,341                  | PCT/GB00/03575                | 117-385          |

FORM PCT/DO/EO/905 (371 Formalities Notice)